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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/757,555 | 01/09/2001 | Levon Michael Khachigian | 273402002020 | 9700 |
| 25226 | 7590 | 12/01/2004 | | |
| MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018 | | | EXAMINER EPPS FORD, JANET L | |
| | | | ART UNIT | PAPER NUMBER |

1635

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,555

Applicant(s)

KHACHIGIAN, LEVON MICHAEL

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/142,779.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's arguments with respect to claim 1-2 and 4-9 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2 and 4-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mendelsohn et al. for the reasons of record set forth in the Office Action mailed 1-09-03. This rejection was mistakenly not included in the Office Action mailed 7-02-03 and 5-05-04.

5. Applicant's arguments filed 4-08-03 have been fully considered but they are not persuasive. Applicants traversed the prior rejection on the grounds that Mendelsohn et al. teaches away from the invention specified in amended claim 1 as there is no motivation to select compounds that inhibit Egr-1 and screen them for the ability to inhibit vascular cells as such agents are **not** candidate vasoprotective agents according to Mendelsohn. Applicants cite the passage in Mendelsohn et al. which states "[a]gents which activate expression of estrogen responsive genes in vascular cells...are candidate vasoprotective agents." ('534 patent, col. 12, lines 24-27). However, contrary to Applicant's assertions, the passage that Applicants are

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referring to represents only one embodiment of the Mendelsohn et al. The invention of Mendelsohn encompasses other alternative embodiments of vasoprotective agents, for example, at col. 1, lines 43-63, it states that the present invention relates to a screening method that can be used to identify agents which inhibit vascular smooth muscle cell activation and/or proliferation or enhance vascular endothelial cell activation and/or proliferation or activate estrogen responsive genes in vascular cells. Therefore, there are several classes of vasoprotective agents described by this reference. Moreover, at col. 11, lines 37-59, it states that preferred vasoprotective agents decrease the expression of egr-1, as indicated by egr-1 (-/-) (see col. 11, line 54). In this case the term “(-/-)” is defined as “(preferred response in vascular endothelial cells/preferred response in vascular smooth muscle cells).” Although it is not specifically indicated in this passage that the overall effect of decreasing egr-1 expression in these cells is inhibition of vascular endothelial and vascular smooth muscle cell proliferation. It would have been obvious to one of ordinary skill in the art to test the ability of the candidate vasoprotective agent for its ability to function as a vasoprotective agent in vascular endothelial cells and smooth muscle cells by utilizing the assay described in Mendelsohn et al. (see col. 12-13).

Moreover, it is noted that the Declaration submitted 10-23-02 was considered by the Examiner in the response filed 1-09-03.

Applicant's arguments do not take the place of evidence that the passage of Mendelsohn et al. at col. 11, line 54, does not encompass wherein the preferred vasoprotective agent functions to reduce the expression of egr-1 in vascular cells.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sells et al. (See IDS filed 9-10-02, reference #3).

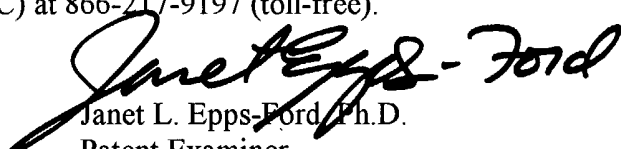
Sells et al. teach the use of an antisense oligonucleotide targeting EGR-1 mRNA to reduce the expression of EGR-1 in melanoma cells. Sells et al. also used a dominant negative mutant of EGR-1 to block the activity of EGR-1 at the protein level. Sells et al. observed that blocking the expression of Egr-1 mRNA and EGR-1 protein activity lead to an acceleration of the IL-1 growth inhibitory response in tumor cells. It was concluded that the function of EGR-1 in melanoma cells was associated with the abrogation of the IL-1 mediated tumor growth inhibitory response. Based upon the teachings of Sells et al. it can be concluded that in the case of melanoma cells, EGR-1 expression is associated with preventing the growth inhibitory effects of IL-1, and inhibition of EGR-1 in melanoma cells by antisense or dominant negative mutants of EGR-1 block the effects of EGR-1 on IL-1 activity, and leads to IL-1 induced tumor growth arrest.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1635

JLE